First results of the **JUPITER Registry** on long-term performance and safety of the **Transapical JenaValve**

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Objectives

- TA-JenaValve received CE-Mark in September 2011
- Post-market registry to evaluate 5-year long-term safety and effectiveness in 180 elderly patients
- Enrollment of consecutive patients to avoid selection bias “Real world” population according to IFU
- Acute and 30-day interim results for first half of the patients

Study design

Methodology

- Intent-to-treat analysis
- Adjudication of major VARC events by independent medical reviewer
- 100% SAE monitoring
- Endpoint definition according to VARC

Endpoints

- Primary 30-day mortality
- Secondary Safety
  Device success
  Effectiveness
  Quality of life (SF-12)

The JenaValve TAVI System

Access route	Transapical
Deployment	Self Expanding
Stent Material	Nitinol
Valve Material	Native Porcine Aortic Valve
Skirt Material	Porcine Pericardium
# of Valve Sizes	3 (23, 25, 27)
Annulus Range	21-27 mm
Delivery System	Cathlete Catheter (sheathless), 3 Step Mechanism
Features	• Feeler guided, anatomically correct positioning • JenaValve Clipping Mechanism • No rapid pacing needed during prosthesis implantation

3 Step Delivery

True anatomically correct positioning with predefined landing zone

Step 1
- Unsheating of feelers
- Orientate the markers
- Tactile feedback
- Anatomically correct positioning

Step 2
- Clipping the JenaValve on the native leaflets
- Less material in the LVOT
- Free left and right ostium

Step 3
- Final valve release
- Correct positioning
- No rapid pacing needed during procedure

Baseline Characteristics

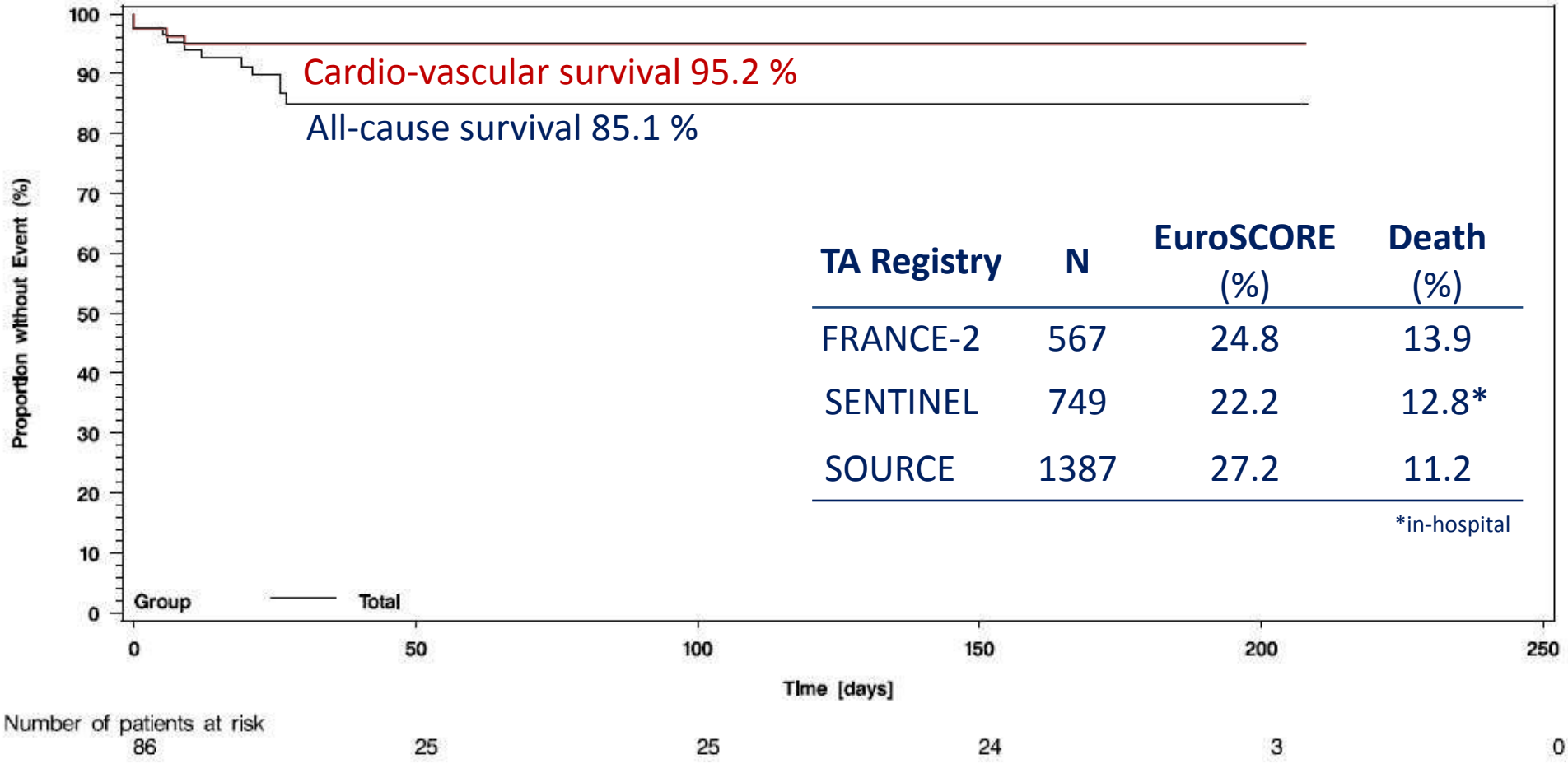
Baseline Characteristics	n=88
Age (years)	80.8 ± 6.1
Female	38.6 % (34)
NYHA class ≥III	85.2 % (75)
Coronary artery disease	46.6 % (41)
Previous CABG	15.9 % (14)
Chronic renal insufficiency	39.8 % (35)
LVEF (%)	51.5 ± 11.6
Logistic EuroSCORE (%)	24.9 ± 13.5
STS Score	6.1 ± 4.1

Procedural Outcomes

Procedural Outcomes		n=88
Native annulus size (mean ± SD)		23.6 ± 1.9
Valve sizes:	23	14.8 % (13)
	25	47.7 % (42)
	27	37.5 % (33)
Duration of TAVI procedure (min)*		8.5 ± 6.6
Procedural success		95.5 %(84)
Valve in valve		2.3 % (2)
Conversion to AVR		2.3 % (2)
Pacemaker implantation (new onset)		12.5 % (11)

* Time from insertion until removal of delivery system

30 day Clinical Outcomes
(according to VARC)



TA Registry	N	EuroSCORE (%)	Death (%)
FRANCE-2	567	24.8	13.9
SENTINEL	749	22.2	12.8*
SOURCE	1387	27.2	11.2

*in-hospital

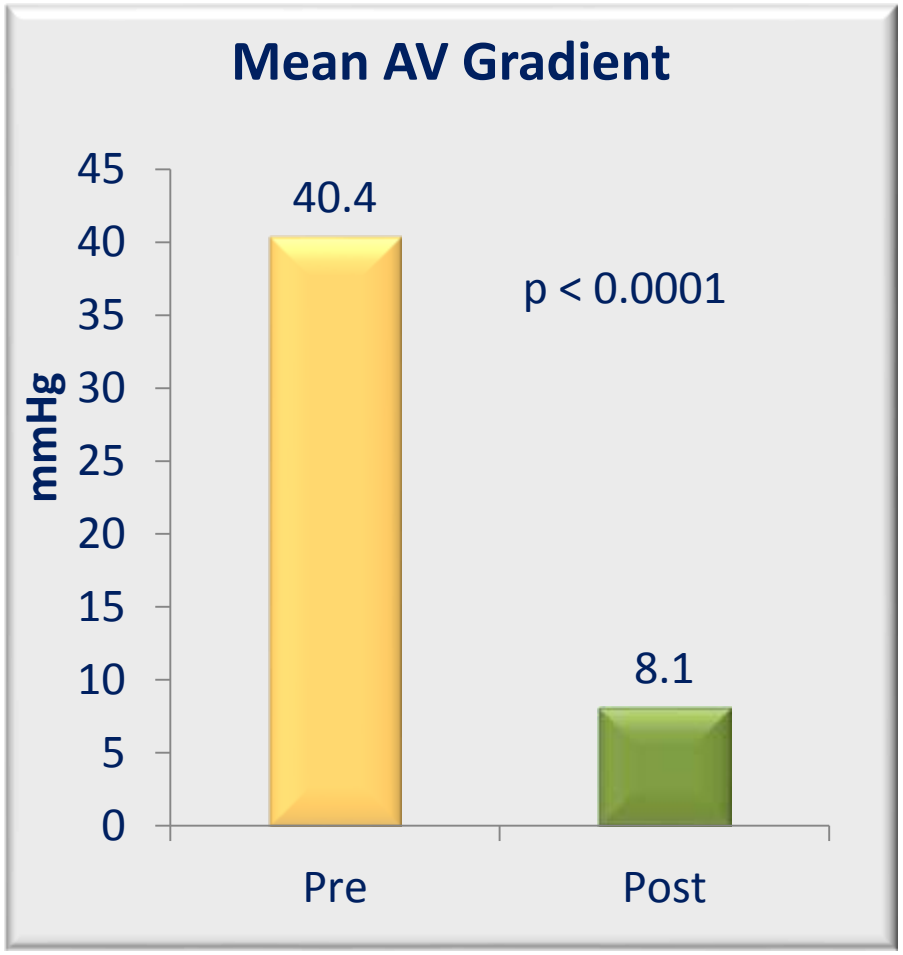
Gilard NEJM 2013; Di Mario EuroIntervention 2012; Wendler EJCTS 2013

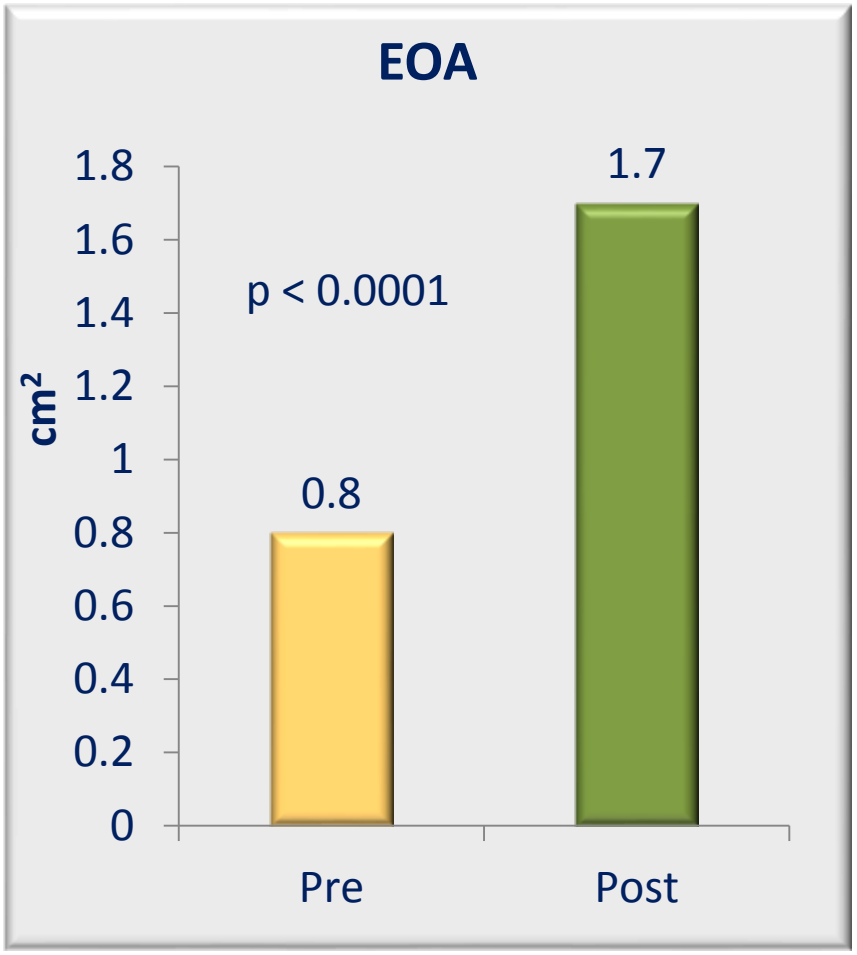
30 day Clinical Outcomes
(according to VARC)

Major events	% (n)
Major stroke	0.0% (0)
Spontaneous myocardial infarction	1.3 % (1)
New onset acute kidney injury (<72h, stage 3)	2.7% (2)
Repeat procedure for valve related dysfunction*	1.3 % (1)

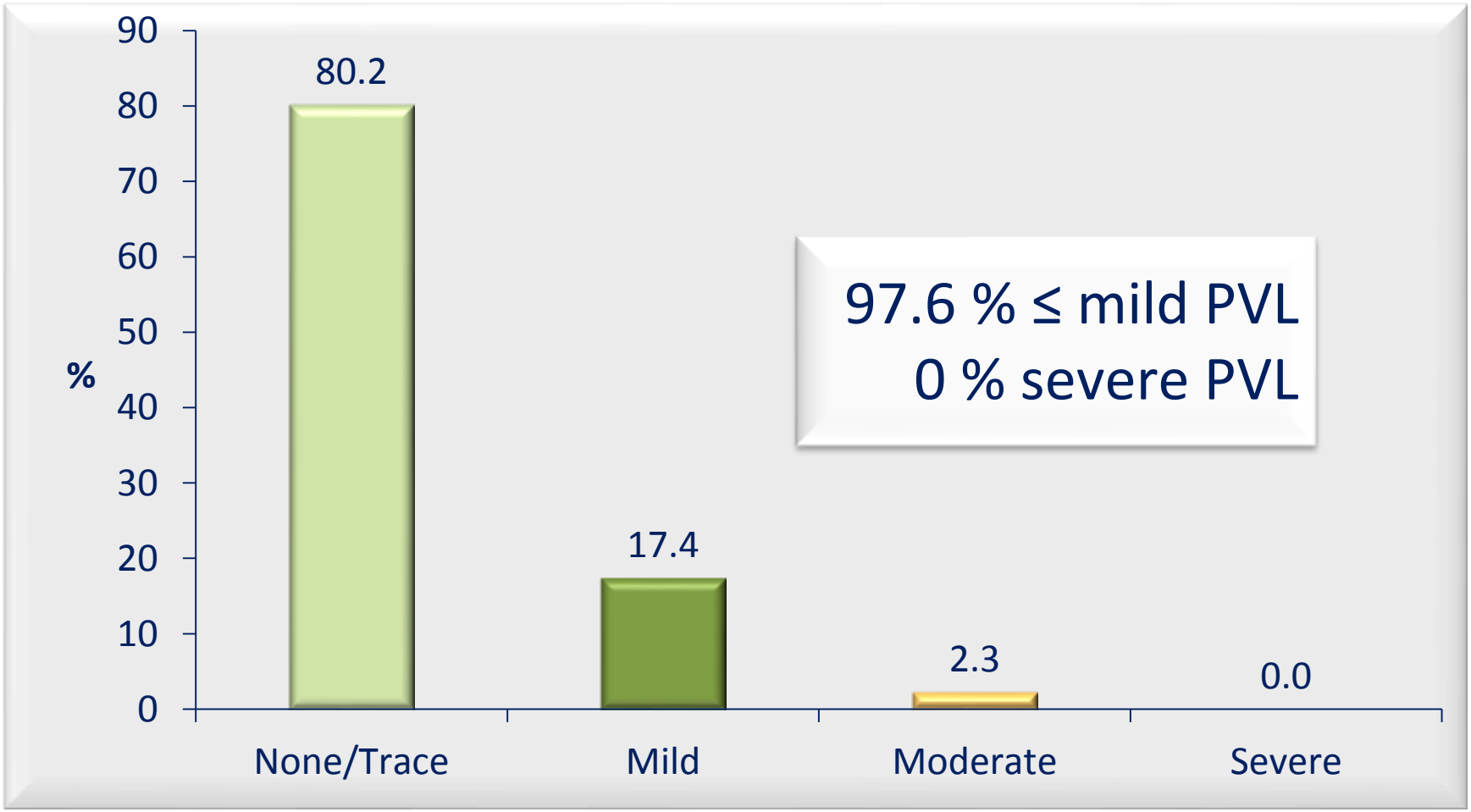
* AVR due to moderate PVL

Echocardiography

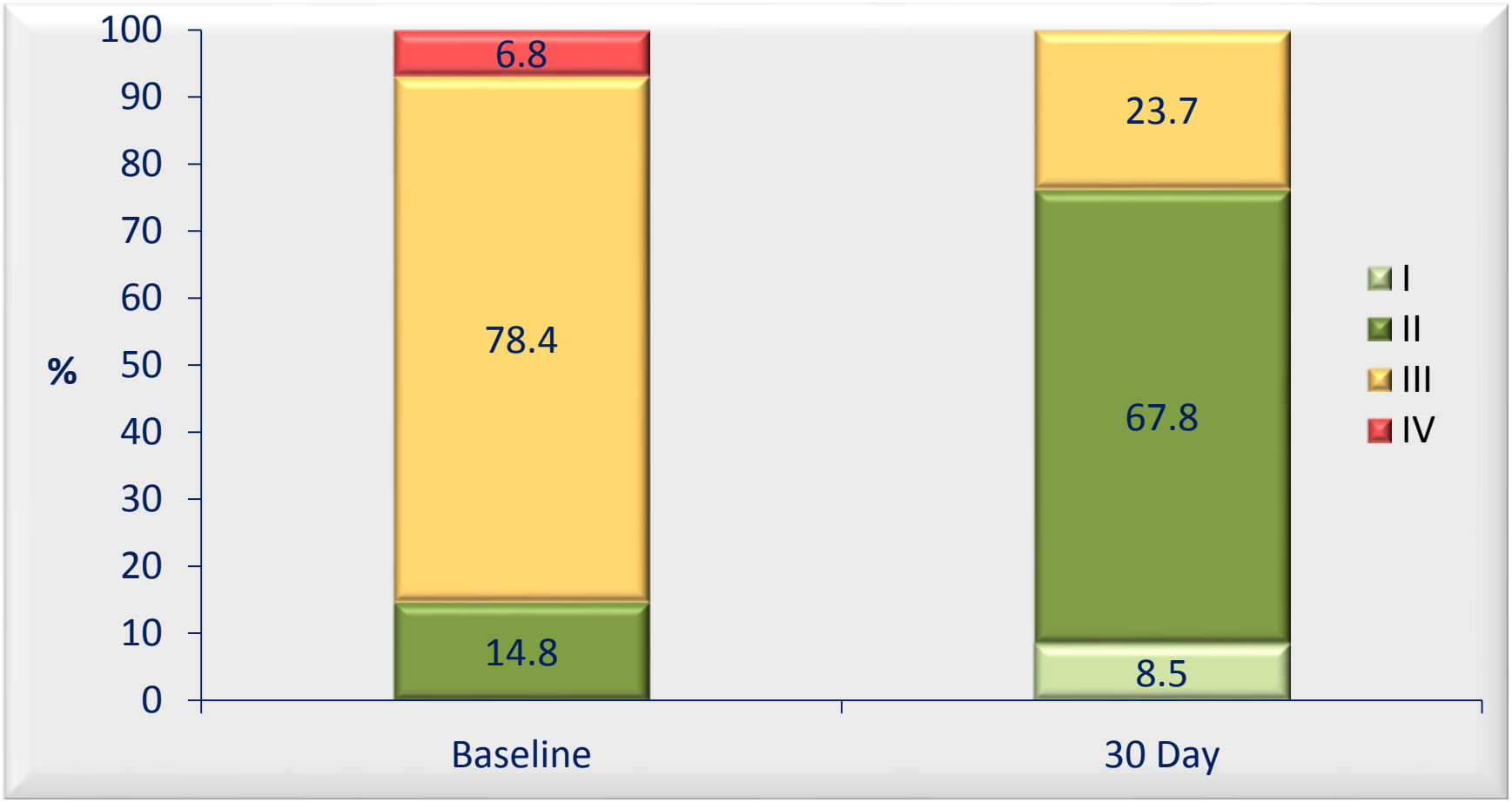




Paravalvular Leakage



NYHA


100
90
80
70
60
50
40
30
20
10
0
%
6.8
78.4
14.8
23.7
67.8
8.5
I
II
III
IV
Baseline
30 Day

Summary

Post Market Registry to evaluate long-term safety and effectiveness of JenaValve (2nd generation TAVI device)

Unique delivery/fixation system of the JenaValve results in:

- High procedural success
- No major stroke
- Excellent haemodynamics
- Low incidence of paravalvular leakage
  97.6 % ≤ mild; 0 % severe